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AGENSYS C/O MORRISON & FOERSTER LLP
12531 HIGH BLUFF DRIVE
SUITE 100
SAN DIEGO, CA 92130-2040

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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/024,652
Filing Date: December 17, 2001
Appellant(s): CHALLITA-EID ET AL.

James Mullen III
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 20 November 2006 appealing from the Office action mailed 12 May 2005.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The following are the related appeals, interferences, and judicial proceedings known to the examiner which may be related to, directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal:

Appellant has appealed the final rejection mailed in U.S. Application 10/280,711.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

No evidence is relied upon by the examiner in the rejection of the claims under appeal.

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 101 and 35 USC § 112, first paragraph

Claims 4, 6-7, 9, 10, 12, 13, 78, and 80-83 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a credible, specific and substantial asserted utility or a well established utility. Novel biological molecules lack well established utility and must undergo extensive experimentation. The basis for these rejections are set forth in the previous Office Actions (02 December 2004; 12 May 2005) and is also fully set forth below.

Specifically, claim 4 is directed to an isolated monoclonal antibody or antibody fragment that specifically binds to a protein having an amino acid sequence of SEQ ID NO: 2570. Claims 6 and 7 recite that the antibody or fragment thereof is recombinantly produced and that the antibody is labeled with a detectable marker. Claim 9 recites that the antibody fragment is selected from the group consisting of Fab, F(ab')2, Fv, and sFv. Claim 10 recites that the antibody is a human antibody, a humanized antibody or a chimeric antibody. Claim 12 is directed to a hybridoma that produces the monoclonal antibody that specifically binds to a protein having an amino acid sequence of SEQ ID NO: 2570. Claim 78 recites that the antibody is labeled with an agent. Claims 80-83 recite that the antibody is labeled with an agent selected from the group consisting of radioactive isotopes, chemotherapeutic agents, and toxins.

However, the instant specification does not teach any significance or functional characteristics of the 108P5H8 polypeptide (SEQ ID NO: 2570) or antibody. The specification discloses that the 108P5H8 protein is normally expressed in a restricted set of normal tissues (including prostate, kidney, brain, testis), but which is also expressed in prostate cancer and other

cancer tissues/cell lines (pg 46, lines 10-11; pg 11; pg 77; Figures 11 and 14; *especially Figures 11A, 11B(lane 3) and 11C*; pg 127, Table I). The 108P5H8 mRNA is not specific to one tissue and the specification discloses nothing about the normal level of expression of the 108P5H8 polypeptide. The specification does not disclose any specific cancers that are associated with altered levels or forms of the 108P5H8 polypeptide. Significant further experimentation would be required of the skilled artisan to identify individuals with such a disease. Also, evidence of mere expression in a tissue is not tantamount to showing a functional role of the 108P5H8 polypeptide. Since this asserted utility is also not present in mature form, so that it could be readily used in a real world sense, the asserted utility is not substantial.

Since the specification does not disclose any methods or working examples that demonstrate the 108P5H8 polypeptide of the instant application exhibits any activity, the skilled artisan would not be able to categorize the polypeptide of the instant application. It is clear from the instant specification that the 108P5H8 polypeptide described therein is what is termed an "orphan protein" in the art. This is a protein whose cDNA has been isolated because of its similarity to known proteins (see for example, bottom of page 75 and pages 119-120 of the specification, Example 42). There is little doubt that, after complete characterization, this protein and antibody may be found to have a specific and substantial credible utility. This further characterization, however, is part of the act of invention and until it has been undertaken, Appellant's claimed invention is incomplete. As discussed in *Brenner v. Manson*, (1966, 383 U.S. 519, 148 USPQ 689), the court held that:

> "The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility", "[u]nless and until a process is refined and developed to this point-where specific benefit exists in currently available form-there is insufficient justification for permitting an applicant to engross what may

> prove to be a broad field", and, "a patent is not a hunting license", "[i]t is not a reward for the search, but compensation for its successful conclusion.

The instant claims are drawn to a monoclonal antibody that specifically binds the 108P5H8 polypeptide, a polypeptide which has an as yet undetermined function or biological significance. Until some actual and specific significance can be attributed to the protein identified in the specification as 108P5H8, the instant invention is incomplete. In the absence of knowledge of the natural substrate or biological significance of this protein, there is no immediately obvious patentable use for it. If the specification discloses nothing specific and substantial about the 108P5H8 polypeptide, therefore both the polypeptide and its antibodies have no patentable utilities. Since the instant specification does not disclose a "real world" use for 108P5H8 then the claimed invention is incomplete and, therefore, does not meet the requirements of 35 U.S.C. § 101 as being useful.

Claims 4, 6-7, 9, 10, 12, 13, 78, and 80-83 are also rejected under 35 U.S.C. § 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

(10) Response to Argument

Appellant argues at the top of page 4 of the Brief that the monoclonal antibodies or antigen binding fragments recited in the claims are useful to treat prostate cancer. Appellant asserts that the specification is replete with explicit assertions regarding the utility of antibodies raised against the 108P5H8 protein for the treatment of cancer. At the bottom of page 4 of the Brief, Appellant indicates that the robust disclosure filed in the case includes other assertions of utility, such as the use of antibodies which recognize the 108P5H8 protein for diagnostic

purposes. Appellant states that these assertions are not presently asserted and whether or not these alternative assertions of utility are operative is of no relevance to the present issue because they are not being asserted. Appellant's arguments have been fully considered but are not deemed to be persuasive for the following reasons. First, the specification of the instant application does not disclose or provide any evidence of a functional property of the 108P5H8 polypeptide of SEQ ID NO: 2570 or explain how that activity can be utilized in a particular therapeutic application (such as prostate cancer treatment). Absent such identification, the 108P5H8 polypeptide has not been researched and understood to the point of providing an immediate, well-defined, real world benefit to the public meriting the grant of a patent. If the specification discloses nothing specific and substantial about the polypeptide, therefore both polypeptide and its antibodies have no patentable utility.

Furthermore, the specification of the instant application discloses that 108P5H8 polypeptide is expressed in both normal and cancerous prostate (pg 11; pg 77; Figures 11 and 14; *especially Figures 11A, 11B(lane 3) and 11C).* Thus, the efficacy of the claimed antibody to target and effectively treat prostate cancer would not be predictable. Furthermore, 108P5H8 mRNA is also expressed nonspecifically on several normal tissues (including kidney, brain and testis) and other cancer tissues/cell lines (pg 11; pg 77; Figures 11 and 14; *especially Figures 11A, 11B(lane 3) and 11C*). Table I at page 127 of the specification lists other malignant tissues that express 108P5H8, including bladder, kidney, colon, lung, ovary, breast, pancreas, uterus, and stomach. Thus, the 108P5H8 mRNA and polypeptide are not specific to one tissue or cancer and the specification discloses nothing about the levels of expression of the 108P5H8 polypeptide in normal and cancerous tissues. No correlation is provided between 108P5H8

expression and a cancerous condition, so predictability of efficacy of the antibody treatment of prostate cancer is unknown and unsupported. Also, evidence of mere expression in a tissue is not tantamount to showing a functional role of the 108P5H8 polypeptide. Since there are many proteins expressed on the surface of a cell (such as a prostate cell), Appellant's asserted therapeutic utility is not specific. Nothing about the asserted utility sets the claimed antibody product apart from other, similar products.

At the middle of page 5 of the Brief, Appellant asserts that sufficient evidence has been provided to convince one of ordinary skill in the art that the presently claimed invention is useful for its intended purpose. At the bottom of page 5 of the Brief, Appellant contends that there is sufficient evidence in the application as filed to support the asserted utility for the claimed invention. Appellant states that the data in Figure 21 and Example 8 of the specification indicates that antibodies made against the 108P5H8 protein were capable of binding to the protein expressed on the surface of prostate cancer cells. At the top of page 6 of the Brief, Appellant argues that Example 8 discusses evidence of antibody binding to the target protein shown in Figures 22-24. Appellant indicates that Examples 50 and 51 discuss using antibody-mediated histochemical procedures to detect the presence of the 108P5H8 marker protein on the surface of prostate cancer cells. Appellant concludes that that data taken as a whole is more than sufficient to provide one of ordinary skill in the art that the claimed antibodies would bind to the 108P5H8 protein on the surface of prostate cancer cells. Appellant's arguments have been fully considered but are not deemed to be persuasive for the following reasons. Specifically, the Examiner acknowledges that polyclonal anti-108P5H8 antibodies bind to the surface of cancer cell lines, cells transfected with 108P5H8 cDNA, and prostate tissue samples. However, the

specification of the instant application discloses that 108P5H8 polypeptide is expressed in both normal and cancerous prostate (pg 11; pg 77; Figures 11 and 14; *especially Figures 11A, 11B(lane 3) and 11C)*. Thus, the efficacy of the claimed antibody to target and effectively treat prostate cancer would not be predictable. Furthermore, 108P5H8 mRNA is also expressed in several normal tissues (including kidney, brain and testis) and other cancer tissues/cell lines (pg 11; pg 77; Figures 11 and 14; *especially Figures 11A, 11B(lane 3) and 11C*). Therefore, the 108P5H8 mRNA and polypeptide are not specific to one tissue or cancer and the specification discloses nothing about the levels of expression of the 108P5H8 polypeptide in normal and cancerous tissues. No correlation is provided between 108P5H8 expression and a cancerous condition, so predictability of efficacy of the antibody treatment of prostate cancer is unknown and unsupported. Additionally there are many proteins expressed on the surface of a cell (such as a prostate cell) and therefore Appellant's asserted therapeutic utility is not specific. Nothing about the asserted utility sets the claimed product apart from other, similar products. Appellant has only disclosed a general use for its claimed antibodies, not specific ones that satisfy 35 U.S.C. § 101. Furthermore, basic research, such as studying the properties of the polypeptide product itself, is required to identify or reasonably confirm a "real world" context of use and, therefore, does not define "substantial utilities". Additionally, MPEP §2107.03 states "[A]s a general matter, evidence of pharmacological or other biological activity of a compound will be relevant to an asserted therapeutic use if there is a reasonable correlation between the activity in question and the asserted utility". The instant application provides no evidence of pharmacological or other biological activity.

At the middle of page 6 of the Brief, Appellant argues that declaratory evidence in support of the asserted utility has been provided during prosecution of the case. Appellant submits that the declaration of Dr. Karen Jane Meyrick Morrison under Rule 1.132 showed immunohistochemistry data where prostate tumor samples were tested with a polyclonal antibody which bound to SEQ ID NO: 2570. Appellant argues that the staining of the tumor sample showed the test antibody bound to the target antigen. Appellant's argument and the declaration of Dr. Karen Jane Meyrick Morrison under Rule 1.132 filed 27 October 2005 have been fully considered but are not deemed to be persuasive for the following reasons. Although the declaration of Dr. Meyrick Morrison does indicate that 108P5H8 protein can be detected on prostate tumor cells, there is no indication as to the detection of 108P5H8 protein on normal prostate cells. The declaration also does not indicate if there is differential expression of 108P5H8 on prostate tumor cells vs. normal prostate cells. The instant specification or declaration provide no correlation between 108P5H8 expression and a cancerous condition, so predictability of efficacy of the antibody treatment of prostate cancer is unknown and unsupported. Until some actual and specific significance can be attributed to the protein identified in the specification as 108P5H8, the instant invention is incomplete. There is little doubt that, after complete characterization, this protein and antibody may be found to have a specific and substantial credible utility. This further characterization, however, is part of the act of invention and until it has been undertaken, Appellant's claimed invention is incomplete. As discussed in *Brenner v. Manson*, (1966, 383 U.S. 519, 148 USPQ 689), the court held that:

> "The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility", "[u]nless and until a process is refined and developed to this point-where specific benefit exists in currently available form-there is insufficient justification for permitting an applicant to engross what may

> prove to be a broad field", and, "a patent is not a hunting license", "[i]t is not a reward for the search, but compensation for its successful conclusion."

Additionally, the teaching of the instant specification that 108P5H8 is expressed in prostate cancer, as well as in several normal tissues (including prostate, kidney, brain, and testis) and cancer tissues/cell lines (pg 11; pg 77; Figures 11 and 14; *especially Figures 11A, 11B(lane 3) and 11C;* pg 127, Table I) does not provide sufficient disclosure to allow those skilled in the art to use 108P5H8 or anti-108P5H8 antibodies, in a specific, real-world use. There are many proteins expressed on the surface of a cell (such as a prostate cell) and therefore, Appellant's asserted therapeutic utility is not specific. Nothing about the asserted utility sets the claimed product apart from other, similar products. Appellant has only disclosed a general use for its claimed antibodies, not specific ones that satisfy 35 U.S.C. § 101.

At the bottom of page 6 of the Brief, Appellant also asserts that the declaration of Dr. Steven B. Kanner demonstrates that the expression of the target protein by normal prostate as well as cancerous prostate cells did not undermine the utility of the invention. Appellant points out that a number of therapeutic antibodies that cross-react with normal tissues are on the market, such as Herceptin® and Erbitux®, and enjoy substantial commercial success. Appellant states that it is well known in the art that these antibodies cross-react with normal tissues other than the targeted cancer tissue. At the top and bottom of page 7 of the Brief, Appellant contends that the declaration of Dr. Kanner shows that one of ordinary skill in the art would not have thought the presently claimed antibodies to lack utility since other therapeutic antibodies that cross react with normal tissues were useful therapeutic agents. Appellant's argument and the declaration of Dr. Steven B. Kanner under Rule 1.132 filed 27 October 2005 have been fully considered but are not deemed to be persuasive for the following reasons. The Examiner acknowledges that therapeutic

monoclonal antibodies are utilized on protein targets that are expressed on both cancerous tissue and normal tissue. However, the *well-characterized* protein targets in these therapies are *overexpressed* in cancerous tissues as compared to normal tissues. For example, Herceptin® is administered to patients with breast cancer whose tumors overexpress the HER2 protein (see Appendix B of the Brief, Herceptin package insert pages 2-3). Likewise, Erbitux® is administered to patients whose tumors have increased levels of epidermal growth factor receptor (EGFR) (see Appendix B of the Brief; Baselga J., Oncologist 7(Suppl 4): 2-8, 2002; page 3 column 2, 1st full paragraph). These other protein targets serve as markers for cancers by their practically useful expression patterns. Such is not the situation in the instant application. There is no indication in the specification or the declarations submitted under 37 CFR 1.132 on 27 October 2005, that there is overexpression or upregulation of 108P5H8 on prostate cancer cells as compared to normal prostate cells. Since 108P5H8 mRNA and protein appear to be expressed in normal prostate and cancerous prostate tissue at similar levels, the asserted utility of treating a cancer that expresses the 108P5H8 protein is not a specific or substantial ("real-world") asserted utility or a well-established utility. Thus, the efficacy of the claimed antibody to target and effectively treat prostate cancer would not be predictable. It is also noted 108P5H8 is nonspecifically expressed in several normal tissues (including kidney, brain and testis) and other malignant tissues (pg 11; pg 77; Figures 11 and 14; *especially Figures 11A, 11B(lane 3) and 11C*; page 127, Table I). Thus, it is clear that the 108P5H8 mRNA and polypeptide are not specific to one tissue or cancer and the specification discloses nothing about the levels of expression of the 108P5H8 polypeptide in normal and cancerous tissues. No correlation is provided in the specification between 108P5H8 expression and a cancerous condition, so

predictability of efficacy of the antibody treatment of prostate cancer is unknown and unsupported. There is no guidance in the specification to indicate that the 108P5H8 polypeptide would confer any selective advantage on a cell expressing it. The 108P5H8 polypeptide has not been researched and understood to the point of providing an immediate, well-defined, real world benefit to the public meriting the grant of a patent.

At the bottom of page 7 of the Brief, Appellant argues that the Office alleged that the asserted utility is not credible but has not stated why one of ordinary skill in the art would believe the invention was completely inoperative. Appellant submits that the data provided in the specification as well as by declaratory evidence shows that antibodies made against the protein of interest are capable of binding to prostate tumor cells. At the top of page 8 of the Brief, Appellant states that given the disposable nature of the prostate organ, cross-reactivity of the antibody with normal and cancerous prostate cells would not be viewed by those or ordinary skill in the art as being detrimental to the utility of the claimed antibodies. Appellant's argument has been fully considered but is not deemed to be persuasive for the following reasons. The truth, or credibility, of the assertion of utility has not been questioned. Rather, the rejection sets forth that the assertion of utility is not specific or substantial. Basic research, such as studying the properties of the polypeptide product itself, is required to identify or reasonably confirm a "real world" context of use and, therefore, does not define "substantial utilities". Additionally, MPEP §2107.03 states "[A]s a general matter, evidence of pharmacological or other biological activity of a compound will be relevant to an asserted therapeutic use if there is a reasonable correlation between the activity in question and the asserted utility". However, regarding the instant application, there is no evidence of pharmacological or other biological activity.

Furthermore, the 108P5H8 mRNA and polypeptide are not specific to one tissue or cancer and the specification discloses nothing about the levels of expression of the 108P5H8 polypeptide in normal and cancerous tissues. There are many proteins expressed on the surface of a cell (such as a prostate cell) and therefore Appellant's asserted therapeutic utility is not specific. Nothing about the asserted utility sets the claimed product apart from other, similar products. Appellant has only disclosed a general use for its claimed antibodies, not specific ones that satisfy 35 U.S.C. § 101.

At the middle of page 8 of the Brief, Appellant asserts that data has been presented to show that the claimed antibodies specifically bind to the 108P5H8 protein, and thus this protein can be used to target cells that express it. Appellant argues that because the protein is expressed on cancerous prostate cells, antibodies that recognize the protein will target those cancerous prostate cells. Appellant concludes that the asserted utility for the claimed antibodies as a treatment for prostate cancer is specific. Appellant's argument has been fully considered but is not deemed to be persuasive for the following reasons. Since 108P5H8 mRNA and protein appear to be expressed in normal prostate and cancerous prostate tissue at similar levels, the asserted utility of treating a cancer that expresses the 108P5H8 protein is not a specific or substantial ("real-world") asserted utility or a well-established utility. The specification also discloses that 108P5H8 is expressed by other normal and malignant tissues, including bladder, testis, kidney, colon, lung, ovary, breast, pancreas, uterus, and stomach (page 11; pg 77; Figures 11 and 14; *especially Figures 11A, 11B(lane 3) and 11;C* page 127, Table I). Notably missing from the specification's disclosure is the teaching of the correlation between expression of the 108P5H8 polypeptide and any cancer. Expression appears to be present in both normal and

cancerous tissues with no discernable pattern or practical correlation. Therefore, the 108P5H8 polypeptide has not been researched and understood to the point of providing an immediate, well-defined, real world benefit to the public meriting the grant of a patent. There is also no guidance in the specification to indicate that the 108P5H8 polypeptide would confer any selective advantage on a cell expressing it. Again, there are many proteins expressed on the surface of a cell (such as a prostate cell) and therefore Appellant's asserted therapeutic utility is not specific. Nothing about the asserted utility sets the claimed product apart from other, similar products. Appellant has only disclosed a general use for its claimed antibodies, not specific ones that satisfy 35 U.S.C. § 101. The specification does not provide sufficient disclosure to allow those skilled in the art to use 108P5H8 or anti-108P5H8 antibodies, in a specific, real-world use.

At the middle of page 9 of the Brief, Appellant disagrees with Examiner's allegation that one of ordinary skill in the art would not be able to use the claimed antibodies to treat prostate cancer if there is not differential expression of the target protein between normal and cancerous prostate cells. Appellant contends that there is nothing in the record or in the art as a whole that would lead one of ordinary skill in the art that the presently claimed invention lacked a substantial utility. Appellant indicates that, as discussed above, other anti-tumor antibodies cross-react with normal tissue yet are effective in the treatment of cancer. Appellant argues that in view of the data provided in the specification as well as the art-recognized need for additional prostate cancer markers, the specification clearly asserts a substantial utility for the claimed invention. At the bottom of page 9 through page 10 of the Brief, Appellant indicates that the prostate is a disposable organ, so the claimed antibodies need not be able to differentiate between normal and cancerous prostate to be useful. Appellant concludes that the presence or absence of

differential expression is not relevant to the question of utility for the claimed invention. Appellant's argument has been fully considered but is not deemed to be persuasive for the following reasons. The Examiner acknowledges that other therapeutic monoclonal antibodies are utilized on protein targets that are expressed on both cancerous tissue and normal tissue. However, the *well-characterized* protein targets in these therapies are *overexpressed* in cancerous tissues as compared to normal tissues. These other protein targets serve as markers for cancers by their practically useful expression patterns. Such is not the situation in the instant application. There is no indication in the specification or the declarations submitted under 37 CFR 1.132 on 27 October 2005, that there is overexpression or upregulation of 108P5H8 on cancer cells as compared to normal cells. Since 108P5H8 mRNA and protein appear to be expressed in normal prostate and cancerous prostate tissue at similar levels, the asserted utility of treating a cancer that expresses the 108P5H8 protein is not a specific or substantial ("real-world") asserted utility or a well-established utility. Thus, the efficacy of the claimed antibody to target and effectively treat prostate cancer would not be predictable. The specification also does not disclose the specific biological activity of the 108P5H8 polypeptide or reasonably correlate that activity to cancer, particularly prostate cancer. There is no guidance in the specification to indicate that the 108P5H8 polypeptide would confer any selective advantage on a cell expressing it. Also, since there are many proteins expressed on the surface of a cell (such as a prostate cell), Appellant's asserted therapeutic utility is not specific. Nothing about the asserted utility sets the claimed product apart from other products. Appellant has only disclosed a general use for its claimed antibodies, not specific ones that satisfy 35 U.S.C. § 101. Although Appellant argues that the prostate is a disposable organ and that the claimed antibodies would

not have to differentiate between normal and cancerous prostate, Appellant is reminded that the specification teaches the 108P5H8 polypeptide is also expressed in normal organs, such as brain and kidney, which are not disposable (see Figures 11, 13).

In conclusion, the 108P5H8 polypeptide and antibody of the instant application (SEQ ID NO: 2570) are not supported by either a credible, specific and substantial ("real-world") asserted utility or a well-established utility. The polypeptide and antibody do not have a substantial utility because basic research is required to study the properties and activity of the polypeptide of SEQ ID NO: 2570 and its binding antibody. Appellant's asserted therapeutic utility for the claimed antibodies is not specific because there are many proteins expressed on the surface of a cell. Nor is it substantial because the 108P5H8 polypeptide is also expressed in several different cancers and cell lines as well as in normal tissues. No correlation is provided between 108P5H8 expression and a cancerous condition, so predictability of efficacy of the antibody treatment of prostate cancer is unknown and unsupported. Nothing about the asserted utility sets the claimed product apart from other products. Appellant has only disclosed a general use for its claimed antibodies, not specific ones that satisfy 35 U.S.C. § 101. Until some actual and specific significance can be attributed to the protein identified in the specification as 108P5H8, the instant invention is incomplete. In the absence of knowledge of the biological significance of this protein, there is no immediately obvious patentable use for it. If the specification discloses nothing specific and substantial about the 108P5H8 polypeptide, therefore both the polypeptide and its antibodies have no patentable utilities. Since the instant specification does not disclose a "real world" use for 108P5H8 then the claimed invention is incomplete and, therefore, does not

meet the requirements of 35 U.S.C. § 101 as being useful. The claims also stand rejected under 35 U.S.C. § 112, first paragraph, for the reasons of record and those set forth above.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Bridget E. Bunner
Art Unit 1647
February 26, 2007

Bridget E. Bunner
BRIDGET BUNNER
PATENT EXAMINER

Conferees:

Brenda Brumback

Yvonne Eyler

Brenda Brumback
BRENDA BRUMBACK
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Yvonne Eyler
YVONNE EYLER, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600